

REMARKS

The applicants appreciate the Examiner's thorough examination of the application and request reexamination and reconsideration of the application in view of the following remarks.

The Examiner rejects claims 1-23 under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,370,685 to *Stevens* in view of U.S. Patent No. 5,830,210 to *Rudko*.

Claim 1 of the subject application is directed to an endovascular tissue removal device comprising a lumen including a rotatable terminal hub advanceable in vasculature, at least one fiber extending from the hub for ablating tissue, and an expandable mechanism connected to the fiber for biasing it into position for precisely ablating tissue as the hub rotates.

The Examiner alleges that *Stevens* discloses an endovascular tissue removal device as claimed except the use of optical energy and delivery optical fibers to provide the tissue removal/treatment energy as presently claimed, and that *Rudko* discloses an alternative endovascular tissue removal device in which plurality of optical fibers disposed on an expandable member deliver ablative laser energy to a desired tissue location. Therefore, the Examiner alleges that at the time of the applicant's invention, it would have been obvious to one skilled in the art to use optical energy and a delivery system as an equivalent alternative means to the mechanical energy of *Stevens* in order to remove a desired vascular tissue.

*Stevens* is directed to a valve system which includes a procedure device capsule connected to a tube and delivered to the site via a guide wire introduced in the femoral artery of a patient. The device capsule houses an expandable barrier attached to balloon segments. Once the guide wire is removed and the barrier is expanded, a tissue cutting blade assembly is advanced in the tube and rotated by a DC motor to resect the existing valve.

*Stevens* describes the cutting assembly in great detail:

The tissue cutter comprises at least one proximal blade and a cable. The proximal blade (45) comprises a collapsible hinged (30) blade of length varying from about 1.0 to 20 millimeters with sharp cutting surfaces. This range of blade length can vary up or down depending on the size of host and lumen. Alternatively, the proximal blade can comprise a flexible wire capable of high speed rotation which would deliver a cutting contact to the tissue. (Col. 6, lines 51-59 of *Stevens*.)

Additional blades can be attached to the proximal blade to increase the cutting ability of the tissue cutter (FIGS. 5,6). For example, two shorter approximately 0.5 to 5.0 millimeter distal blades (40) can be attached through melding, hinging, or other connecting methods, to the distal ends of the proximal blade. This blade length range can vary up or down in size depending on the size of host and lumen. (Col. 6, lines 65-Col. 7, line 5 of *Stevens*.)

The disclosure of *Stevens* makes it clear that the valve replacement system, and especially the cutting assembly, are purely mechanical systems.

Further, it would not have been obvious to one skilled in the art to look to *Rudko* to modify *Stevens*. As noted above, *Rudko* is directed to a catheter navigation apparatus for guiding the targeting of a treatment catheter in percutaneous transmyocardial revascularization procedures. In such procedures, a laser is used to drill holes in the myocardium.

As shown above, *Stevens* fails to disclose, teach or suggest using ablation energy to resect the heart valve. *Stevens* only discloses using mechanical blades to cut the heart valve. Further, *Rudko* fails to disclose, teach or suggest resection of a heart valve in any manner. *Rudko* only discloses using ablation energy to drill holes in the myocardium.

One skilled in the art would not look to *Rudko* to modify *Stevens* as *Rudko* does not disclose, teach or suggest anything relating to heart valve resection, which is the sole focus of *Stevens*.

In this case, it is only by way of the applicants' specification for the claimed invention,

using impermissible hindsight, that the references would be combined.

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field ... Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher'." In re Kotzab, 217 F.3d 1365, 1369, 55 USPQ 2d 1313, 1316 (Fed. Cir. 2000), quoting W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983).

To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. See In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ 2d 1313, 1316 (Fed. Cir. 2000).

The law is further clear that the teaching of the desirability of combining the references must not come from the applicant's invention. "There must be a reason or suggestion in the art for selecting the procedure used, *other* than the knowledge learned from the applicants' disclosure." See In re Dow Chemical Company, 837 F.2d 469, 473, 5 USPQ 2d 1529, 1532 (Fed. Cir. 1989) (with emphasis added).

*Stevens* does not provide any motivation, teaching or suggestion to replace the mechanical cutting blades with an ablative optical energy cutting system as claimed by the applicant. Indeed, to modify *Stevens* in such a manner, the entire cutting device of *Stevens* would have to be removed and replaced with an optical system for which *Stevens* provides no support, as *Stevens* is a purely mechanical device.

Further, it would not have been obvious to one skilled in the art to look to *Rudko* to modify *Stevens*. As noted above, *Rudko* is directed to a catheter navigation apparatus for guiding

the targeting of a treatment catheter in percutaneous transmyocardial revascularization procedures. In such procedures, a laser is used to drill holes in the myocardium. As the sole purpose of *Stevens* is to remove an aortic valve by cutting the valve from the heart, one would not look towards a reference which teaches the use of ablative optical energy only to drill holes in tissue, and not to remove sections of tissue. Nowhere does *Rudko* disclose, teach or suggest the use of ablative optical energy to remove sections of tissue. Thus, those of skill in the art would not look to *Rudko* to modify *Stevens*.

Accordingly, claims 1-23 are patentable over the cited references.

Additionally, independent claim 23 also includes the feature of a second lower balloon 100 is disposable on the ventricular side of the heart valve under leaflets 102 and 104. Balloon 100 is connected to inflation conduit 106 which extends within multi-lumen catheter 81. An outer suction conduit may include port 110 for withdrawing tissue. Balloon 100 performs several important functions. First, it supports leaflets 102 and 104 of the valve as they are pushed closed by tissue removal device 80 before cutting for more accurate cutting. Balloon 100 with laser energy absorption or layer 112 also prevents inadvertent cutting of any portion of mitral valve 116. See Figs. 5A and 8B of the subject application.

Neither *Stevens* nor *Rudko* disclose any type of expandable mechanism introducible to the ventricular side of a valve to support the leaflets of the valve in a closed position as claimed by the applicant in the subject application. As neither of the references disclose the expandable mechanism as claimed by the applicant, independent claim 23 is patentable over *Stevens*, either alone or in combination with *Rudko*.